



SMALLPOX FREQUENTLY ASKED QUESTIONS

In General

What should I know about smallpox?

Smallpox is an acute, contagious and sometimes fatal disease caused by the variola virus (an orthopoxvirus) and marked by fever and a distinctive progressive skin rash. In 1980, the disease was declared eradicated following worldwide vaccination programs. However, in the aftermath of the events of September and October 2001, the United States is taking precautions to be ready to deal with a bioterrorist attack using smallpox as a weapon. As a result of these efforts:

1. There is a detailed nationwide smallpox response plan designed to vaccinate people quickly and contain a smallpox outbreak. The plan includes the creation and vaccination of smallpox healthcare teams who would respond to a smallpox emergency.
2. There is enough smallpox vaccine to vaccinate everyone who would need it in the event of an emergency.

How serious is the smallpox threat?

The deliberate release of smallpox as an epidemic disease is now regarded as a possibility, and the United States is taking precautions to deal with this possibility.

How dangerous is the smallpox threat?

Smallpox is classified as a Category A agent by the Centers for Disease Control and Prevention. Category A agents are believed to pose the greatest potential threat for adverse public health impact and have a moderate to high potential for large-scale dissemination. The public is generally more aware of category A agents, and broad-based public health preparedness efforts are necessary. Other Category A agents are anthrax, plague, botulism, tularemia, and viral hemorrhagic fevers.

If I am concerned about a smallpox attack, can I go to my doctor and get the smallpox vaccine?

At the moment, the smallpox vaccine is not available for members of the general public. In the event of a smallpox outbreak, however, there is enough smallpox vaccine to vaccinate everyone who would need it.

The Disease

What are the symptoms of smallpox?

The symptoms of smallpox begin with high fever, head and body aches, and sometimes vomiting. A rash follows that spreads and progresses to raised bumps and pus-filled blisters that crust, scab and fall off after about three weeks, leaving a pitted scar.

If someone comes in contact with smallpox, how long does it take to show symptoms?

After exposure, it takes between seven and 17 days for symptoms of smallpox to appear. (Average incubation time is 12 to 14 days.) During this time, the infected person feels fine and is not contagious.

Is smallpox fatal?

The majority of patients with smallpox recover, but death may occur in up to 30 percent of cases. Many smallpox survivors have permanent scars over large areas of their body, especially their face. Some are left blind.

How is smallpox spread?

Smallpox normally spreads from contact with infected persons. Generally, direct and fairly prolonged face-to-face contact is required to spread smallpox from one person to another. Smallpox also can be spread through direct contact with infected bodily fluids or contaminated objects such as bedding or clothing. Indirect spread is less common. Rarely, smallpox has been spread by virus carried in the air in enclosed settings such as buildings, buses and trains. Smallpox is not known to be transmitted by insects or animals.

If smallpox is released in aerosol form, how long does the virus survive?

The smallpox virus is fragile. In laboratory experiments, 90 percent of aerosolized smallpox virus dies within 24 hours; in the presence of ultraviolet (UV) light, this percentage would be even greater. If an aerosol release of smallpox occurs, 90 percent of virus matter will be inactivated or dissipated in about 24 hours.

How many people would have to get smallpox before it is considered an outbreak?

One confirmed case of smallpox is considered a public health emergency.

Is smallpox contagious before the smallpox symptoms show?

A person with smallpox is sometimes contagious with onset of fever (prodrome phase), but the person becomes most contagious with the onset of rash. The infected person is contagious until the last smallpox scab falls off.

Is there any treatment for smallpox?

Smallpox can be prevented through use of the smallpox vaccine. There is no proven treatment for smallpox, but research to evaluate new antiviral agents is ongoing. Early results from laboratory studies suggest that the drug cidofovir may fight against the smallpox virus; currently, studies with animals are being done to better understand the drug's ability to treat smallpox disease. (The use of cidofovir to treat smallpox or smallpox reactions should be evaluated and monitored by experts at NIH and CDC.) Patients with smallpox can benefit from supportive

therapy (e.g., intravenous fluids, medicine to control fever or pain) and antibiotics for any secondary bacterial infections that may occur.

The Vaccine

What is the smallpox vaccine, and is it still required?

The smallpox vaccine is the only way to prevent smallpox. The vaccine is made from a virus called *vaccinia*, which is another “pox”-type virus related to smallpox but cannot cause smallpox. The vaccine helps the body develop immunity to smallpox. It was successfully used to eradicate smallpox from the human population.

Routine vaccination of the American public against smallpox stopped in 1972 after the disease was eradicated in the United States. Until recently, the U.S. government provided the smallpox vaccine only to a few hundred scientists and medical professionals who work with smallpox and similar viruses in a research setting.

After the events of September and October 2001, however, the U.S. government took further actions to improve its level of preparedness against terrorism. For smallpox, this included updating a response plan and ordering enough smallpox vaccine to immunize the American public in the event of a smallpox outbreak. The plans are in place, and there is sufficient vaccine available to immunize everyone who might need it in the event of an emergency.

In addition, the Bush Administration recently announced a plan to better protect the American people against the threat of smallpox attack by hostile groups or governments. This plan included the creation of smallpox healthcare teams that would respond to a smallpox emergency. Members of these teams would be vaccinated against smallpox. The plan also included vaccination of military and civilian personnel who are or may be deployed in high threat areas.

Should I get vaccinated against smallpox?

The smallpox vaccine is not available to the public at this time.

How is the vaccine given?

The smallpox vaccine is not given with a hypodermic needle. It is not a “shot,” like many vaccinations. The vaccine is given using a bifurcated (two-pronged) needle that is dipped into the vaccine solution. When removed, the needle retains a droplet of the vaccine. The needle is then used to prick the skin a number of times in a few seconds. The pricking is not deep, but it will cause a sore spot and one or two drops of blood to form. The vaccine usually is given in the upper arm.

If the vaccination is successful, a red and itchy bump develops at the vaccination site in three or four days. In the first week after vaccination, the bump becomes a large blister, fills with pus and begins to drain. During week two, the blister begins to dry up and a scab forms. The scab falls off in the third week, leaving a small scar. People who are being vaccinated for the first time may have a stronger “take” (a successful reaction) than those who are being revaccinated.

Many vaccinations are required. Why don't people have to get the smallpox vaccine?

The last case of smallpox in the United States was in 1949. The last naturally occurring case in the world was in Somalia in 1977. After the disease was eliminated from the world, routine vaccination against smallpox among the general public was stopped because it was no longer necessary for prevention.

If someone is exposed to smallpox, is it too late to get a vaccination?

Vaccination within three days of exposure will completely prevent or significantly modify smallpox in the vast majority of persons. Vaccination 4 to 7 days after exposure likely offers some protection from disease or may modify the severity of disease.

How long does a smallpox vaccination last?

Past experience indicates that the first dose of the vaccine offers protection from smallpox for three to five years, with decreasing immunity thereafter. If a person is vaccinated again later, immunity lasts longer.

Are diluted doses of smallpox vaccine as effective?

Recent tests have indicated that diluted smallpox vaccine is just as effective in providing immunity as full-strength vaccine.

Vaccinia

What is the smallpox vaccine made of?

The vaccine is made from a virus called *vaccinia*, another “pox”-type virus related to smallpox but that does not cause smallpox. The smallpox vaccine helps the body develop immunity to smallpox. It does not contain the smallpox virus and cannot spread smallpox.

Is it possible for people to get smallpox from the vaccination?

No. The smallpox vaccine does not contain smallpox virus and cannot spread or cause smallpox. However the vaccine does contain another virus called vaccinia, which is “live” in the vaccine. Because the virus is live, it can spread to other parts of the body or to other people from the vaccine site. This can be prevented through proper care of the vaccination site (e.g., hand washing and careful disposal of used bandages).

Is it possible to get vaccinia, the virus in the vaccine, from someone who has recently been vaccinated?

Yes. Vaccinia is spread by touching a vaccination site before it has healed or by touching bandages or clothing that have become contaminated with live virus from the vaccination site. Vaccinia is not spread through airborne contagion. The vaccinia virus may cause rash, fever, and head and body aches.

Vaccine Safety

How safe is the smallpox vaccine?

The smallpox vaccine is the best protection you can get if you are exposed to the smallpox virus.

Most people experience normal, usually mild reactions that include a sore arm, fever, and body aches. In recent tests, one in three people felt bad enough to miss work, school or recreational activity or had trouble sleeping after receiving the vaccine.

However, the vaccine does have some risks. In the past, about 1,000 people for every one million people vaccinated for the first time experienced reactions that, while not life-threatening, were serious. These reactions include a vigorous (toxic or allergic) reaction at the site of the vaccination and spread of the vaccinia virus (the live virus in the smallpox vaccine) to other parts of the body and to other people. These reactions typically do not require medical attention.

Rarely, people have had very bad reactions to the vaccine. In the past, between 14 and 52 people per 1 million vaccinated experienced potentially life-threatening reactions, including eczema vaccinatum, progressive vaccinia (or vaccinia necrosum), or postvaccinal encephalitis. Based on past experience, it is estimated that between one and two people out of every one million people vaccinated will die as a result of life-threatening reactions to the vaccine. Careful screening of potential vaccine recipients is essential to ensure that those at increased risk do not receive the vaccine.

People most likely to have side effects are people who have, or even once had, skin conditions, (especially eczema or atopic dermatitis) and people who have weakened immune systems, such as those who have received a transplant, are HIV positive, or are receiving treatment for cancer. Anyone who falls within these categories, or lives with someone who falls into one of these categories, should NOT get the smallpox vaccine unless they are exposed to the disease. Pregnant women should not get the vaccine because of the risk it poses to the fetus. Women who are breastfeeding should not get the vaccine. Children younger than 12 months of age should not get the vaccine. Also, the Advisory Committee on Immunization Practices (ACIP) advises against non-emergency use of smallpox vaccine in children younger than 18.

Who should NOT get the vaccine?

Individuals who have any of the following conditions, or who live with someone who does, should not get the smallpox vaccine **unless they have been exposed to the smallpox virus:**

- Skin conditions, especially eczema and atopic dermatitis – even if the condition is not currently active, is mild or was experienced as a child.
- Weakened immune systems. (Cancer treatment, an organ transplant, HIV or medications (like steroids) that suppress the immune system.
- Skin conditions such as burns, chickenpox, shingles, impetigo, herpes, severe acne or psoriasis. (These people should wait until they have completely healed.)
- Pregnancy or plans to become pregnant within one month of vaccination.

In addition, individuals should not get the smallpox vaccine if they:

- Have been diagnosed by a doctor as having a heart condition with or without symptoms OR if they have three or more cardiac risk factors.
- Are allergic to the vaccine or any of its components.
- Are younger than 12 months of age. However, the Advisory Committee on Immunization Practices advises against non-emergency use of smallpox vaccine in children younger than 18 years of age.
- Have a moderate or severe short-term illness. (These people should wait until they have completely recovered.)
- Are currently breastfeeding.

People who have been directly exposed to the smallpox virus should get the vaccine – regardless of their health status – after first consulting a physician or health care provider.

Should you get the smallpox vaccine if you have a weakened immune system (e.g., you are immunocompromised)?

No, you should not be vaccinated, unless there is a smallpox outbreak and you have been directly exposed to the smallpox virus. Vaccination can cause deaths in people with weakened immune systems. Thus, there is no need to take the risks associated with smallpox vaccination unless you have been directly exposed to smallpox — and even then, you should first consult a physician or health care provider.

Pregnant women are discouraged from getting the vaccine. Is there a danger to them (or to an unborn child) if broader vaccination occurs, increasing the potential for contact with vaccinated people?

Pregnant women should NOT be vaccinated in the absence of a smallpox outbreak because of risk of fetal infection. Inadvertent transmission of vaccinia virus to a pregnant woman also could put the fetus at risk. Vaccinated people must be very cautious to prevent transmission of the vaccine virus to pregnant women or other contacts.

Is there any way to treat bad reactions to the vaccine?

Two treatments may help people who have certain serious reactions to the smallpox vaccine. These are Vaccinia Immune Globulin (VIG) and cidofovir. By the end of December 2002, there will be more than 2,700 treatment doses of VIG (enough for predicted reactions with more than 27 million people) and 3,500 doses of cidofovir (enough for predicted reactions with 15 million people). Additional doses of VIG are being produced, and measures are underway to increase supplies of cidofovir as well. VIG and cidofovir are both administered under investigational new drug (IND) protocol.